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Fat graft myringoplasty – A prospective clinical study

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KEYWORDS

Myringoplasty;
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 Post-operative residual
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Abstract A prospective clinical study for reporting the efficacy of fat grafting for small tympanic membrane perforations due to: trauma, infection, post-tympanostomy tube extraction and post myringoplasty residual perforations. Also, to emphasize upon the clinical criteria and technical operative points needed for the success of this procedure.

Sixty patients aged between 4 to 44 years; with fat graft myringoplasty were operated for closure of tympanic membrane perforation due to the above causes. Follow up visits for tympanic membrane evaluation, were in the 1st, 4, 6 and 12th post-operative months. Failure cases were counted at the end of the 1st month post-operatively. Hearing evaluation was done pre-operatively and in the 4th postoperative month. Closure of the air bone gap was the parameter of hearing improvement. The outcome measures were the post-operative state of tympanic membrane, hearing improvement in closure of the air-bone gap and incidence of failures and complications.

The Mean operative time was 20 minutes. No side effects or operative complication occurred. The successful procedures were (88.2%) from the entire patient group. Post-operatively, the mean improvement in the air/bone gap was about 15 dB for the successful cases. The success rate for each group was: (89%) for post-tympanostomy tube extraction persistent perforations, (90%) for post traumatic persistent perforations and (86.6%) for each of chronic tubotympanic inactive suppurative otitis media with perforation and post myringoplasty residual perforation.

Conclusion: Fat graft myringoplasty is an easy, simple, fast and minimally invasive procedure for the repair of small tympanic membrane perforations with favorable hearing results.

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1. Introduction

Tympanic membrane perforations are common ear disorders diagnosed by the otolaryngologist. Their aetiology occurs under a variety of causes mainly: trauma, infection, post-tympanostomy tube extraction or residual perforation after an attempt for surgical repair. When those tympanic membrane perforations are small and persistent, the hearing reduction is usually mild but the middle ear mucosa is exposed in this

condition to the external environment by the defect of ear drum. Through this defect: water, sweat, discharge of the external ear canal if infected or even variation in external temperature, can reach directly the middle and inner ears causing infection or damage and progressive hearing loss. Warmald,¹ has defined the surgical closure of the tympanic membrane perforation without ossicular reconstruction as myringoplasty. Fat is an accepted material used for small tympanic membrane perforation reconstruction in the literature.²⁻⁷ The aim of the work was to report the efficacy of fat graft myringoplasty for small tympanic membrane perforations due to: trauma, infection, post tympanostomy tube extraction and post myringoplasty residual perforations. Also, this study was to emphasize upon the clinical criteria and technical operative points needed for the success of fat graft myringoplasty.

2. Patients and methods

The patients in this prospective clinical study were selected, operated and followed up over the period of January 2009 to January 2012. The author applied the clinical criteria published by Fiorio and Barbieri 4 (table 1), for the selection of cases for fat graft myringoplasty; any patient who did not fulfil those criteria was excluded from the study. The causes of the tympanic membrane perforations chosen for this research were: post-traumatic persistent perforation (10 ears), chronic tubotympanic inactive suppurative otitis media with perforation (15 ears), post tympanostomy tube extraction persistent perforation (28 ears) and post myringoplasty residual perforation (15 ears). All patients were informed about the idea of the operation, the place from where the fat is harvested (ear lobe or abdominal fat). Informed consent was obtained after discussion of the alternatives from only watchful follow up to a traditional myringoplasty. The consent of the institutional review board was obtained. Sixty patients were included in this study, 29 males and 31 females, aged between 4 and 44 years. All had suffered unilateral or bilateral chronic tympanic membrane perforations with complaint of hearing loss. All patients underwent full ENT history taking, a thorough clinical examination, full audiometric and Eustachian tube function testing and full laboratory preoperative testing. The evaluation of hearing was done pre-operatively and in the 4th post-operative month. The amount of closure of the air bone gap at 0.5, 1, 2, 4 kHz was the parameter of hearing improvement.

2.1. Technique

All procedures were performed under general anaesthesia using laryngeal masks. The patient was positioned on his/her back in the anti-trendelenberg position with shoulder support elevating the shoulders 5 cm. A head ring should be placed under the head with rotation of it away from the surgeon and making the operated ear superior. The operated ear was prepared and draped under sterile conditions. With the help of the operating microscope, the margins of the perforation were refreshed by de-epithelializing along the margins by a needle or sharp dissector and a micro crocodile forceps. The final size of the perforation after refreshing its margins was done to estimate the amount of fat needed for grafting.

The ear lobe was infiltrated using 2% lidocaine with 1:100,000 adrenaline and a 5 mm incision was made at the

Table 1 Criteria followed for admission to fat graft myringoplasty 4.

1. Period of time elapsed from previous surgery equal to or longer than 6 months.
2. Perforation of the pars tensa no larger than 5 mm.
3. Non-marginal localization, i.e. not involving the annulus or exposing the malleus handle.
4. Absence of calcific plaques or atrophic areas adjacent to the perforation.
5. Normal appearance of mucosa in the tympanic cavity.
6. Absence of any acute inflammation.
7. Absence of middle ear discharge in last 3 months.
8. No evidence of cholesteatoma.
9. No planned ossicular reconstruction.
10. Absence of major Eustachian tube dysfunction.

medial surface of the tip of the ear lobe with no. 15 blade. The skin was undermined and an amount of fat as twice as the size of the perforation was harvested in one piece and was put in a sterile saline solution. The incision was closed by one or two 5-0 absorbable sutures. In 10 cases, fat was harvested from the abdomen through a periumbilical incision by the same method of ear lobe.

Under microscopic vision, the fat was trimmed at an approximately twice the size of the perforation or lesser. It was placed over the perforation and plugged in it as an hour-glass through the perforation using a pick or blunt needle. The lateral fat bulge should not be too high to help epithelial closure of the perforation. Oversized fat plug may cause a tear in the tympanic membrane or overstretching of the perforation margins leading to atrophy or necrosis later on.

Undersized fat plug should be avoided to prevent dehiscence in grafting.

The graft was kept humidified by pieces of gelfoam upon and around the outer portion of the fat and stabilized by using a sialastic sheet covering the tympanic membrane and the lateral outer side of the graft. The external ear is filled with pieces of gelfoam soaked with local antibiotic drops (fig. 1). The external ear opening is sealed with a merocel ear pack. No ear dressing was used.

After recovery from anaesthesia, the patient was discharged on the same day with home medications comprising proper antibiotics, analgesics and nasal decongestant spray for one week. The patient was instructed to keep the ear dry, avoid straining or nose blowing for at least 4 weeks. The merocel pack was removed after 1 week and the gel foam with the sialastic sheet was removed under microscopic vision at the end of the 3rd week. Local antibiotic drops were prescribed for 2 weeks after removal of the sialastic sheet and gel foam. Follow up visits, for the tympanic membrane evaluation, were in the 1st, 4th, 6th and 12th post-operative months. Failure cases were counted when the relapsing perforation occurs and persists until the end of the 1st month post operatively.

The outcome measures of this study were the post operative state of tympanic membrane, hearing improvement in the form of closure of the air-bone gap and incidence of complications e.g. infection, adhesions or residual defects in the tympanic membrane after fat graft myringoplasty.

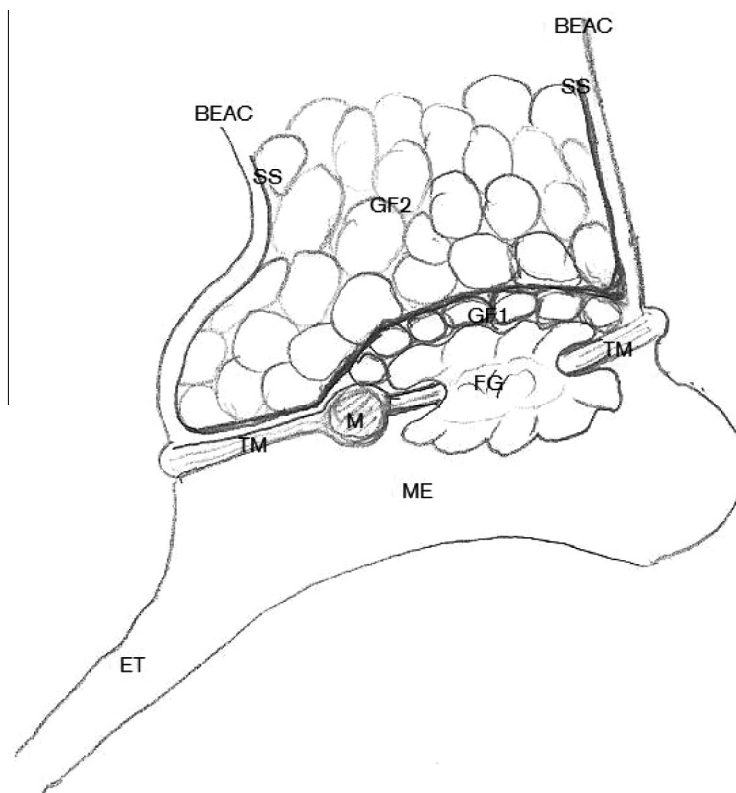


Figure 1 Fat graft in place (cross section), BEAC: Bony external auditory canal, ET: Eustachian tube, FG: Fat graft, GF1: Gel foam pieces around the graft, GF2: Gel foam pieces filling the sialistic sheet and the canal, M: Malleus handle, SS: Sialistic sheet, TM: Tympanic membrane.

3. Results

Sixty patients were included in this study, 52 patients had unilateral, while eight patients had bilateral perforations with a total number of 68 ear perforations, who had fat graft myringoplasty, included in this study. The eight bilateral perforation cases were all due to post-long term tympanostomy tube extraction and the selection of which ear to be operated upon was the ear with a larger air bone gap. If both air bone gaps are equal, the larger perforation was operated first. The second ear was operated upon after 3 months of complete healing of the 1st ear.

There was no side effect or complication at the time of the procedures. The mean operative time for the procedure counted from the beginning of the marginal refreshment of the perforation to closure of external ear canal by merocel pack was 20 min.

There were 60 out of 68 successful procedures (88.2%) from the entire patient group. The remaining 8 failures of perforation closure included: three cases due to postoperative infection and graft necrosis, three cases due to failure of the patient to follow the postoperative instructions which led to graft detachment and the last two cases from the early cases of the study due to the use of an undersized fat graft which led to dehiscence and residual perforation. (Tables 2 and 3).

According to the causes of perforation included in this study: the success rate for each group of ears was: 25/28 (89%) for post-tympanostomy tube extraction persistent perforations, 9/10 (90%) for post traumatic persistent

perforations and 13/15 (86.6%) for each of chronic tubotympanic inactive suppurative otitis media with perforation and post myringoplasty residual perforation cases. The success rate did not change whatever be the underlying cause of perforation (Table 2).

The pre and post operative air bone gap are detailed statistically in table 4. The air/bone gap of the entire patient group was ranging between 10 and 20 dB preoperatively. Post operatively, the mean improvement in the air/bone gap was about 15 dB for the successful cases. The present work revealed that fat grafting of tympanic perforation of the (68) operated ears resulted in a significant reduction of the range of air-bone gap from 15 to 20 dB among 96.66% of the operated ears with an average of 19.75 ± 1.434 preoperatively compared to a range of 0–5 dB among 91.7% of the operated ears with an average of 5 ± 1.058 dB postoperatively (Table 4).

4. Discussion

The principal aim of fat graft myringoplasty is the complete closure of the small tympanic membrane perforations with a simple, short, cost effective, procedure least in pain and trauma to the healthy ear drum due to the absence of skin incisions, dissections of meatal flaps and fewer complications with maximum improvement of the air/bone gap after the procedure.^{3,4}

Although fat graft myringoplasty is a simple, safe and cost-effective procedure, it has been underused despite its numerous advantages.⁷ However, it cannot be always an alternative

Table 2 Success and failure rates according to cause of tympanic perforation.

Cause of tympanic perforation (no.)	Success no. (%)	Failure no. (%)
Post tympanostomy tube extraction	25(89.0)	3(11.0)
Post traumatic	9(90.0)	1(10.0)
Chronic tubotympanic inactive suppurative otitis media	13(86.6)	2(13.4)
Post myringoplasty residual perforation	13(86.6)	2(13.4)
Total	60(88.2)	8(11.8)

Table 3 Factors behind failure of fat grafting among the operated ears.

Underlying factors	No. (%)
Graft necrosis (due to postoperative infection)	3(37.5)
Graft detachment (due to failure to follow postoperative instruction)	3(37.5)
Undersized fat graft	2(25.0)
Total	8(100.0)*

* 11.8% Of the operated ears.

Table 4 Pre-and post-operative air-bone gap.

Air-bone gap (dB)	No. of ears (%)					Mean (SD)
	≤0	1–5	6–10	11–15	15–20	
Pre-operative	–	–	1(1.66)	1(1.66)	58(96.66)	19.75(1.434)
Post-operative	5(8.33)	50(83.33)	5(8.33)	–	–	5(1.058)
Significance	$P = 0.001^a$					$P = 0.000^b$

^A For Fisher exact test.

^B For Student's "t" test.

procedure to the classic surgical myringoplasty in every tympanic membrane perforation. Certain clinical criteria should be fulfilled and applied for the perforation to have the highest possibility of this procedure's success. The clinical criteria established by Fiorino and Barbieri⁴ for admission to fat graft myringoplasty were sufficient for the selection of patients eligible for this procedure (Table 1).

The first utilization of fat plug myringoplasty was reported by Ringenberg⁸, with the success rate of 87%. In the following studies the success rate was ranging from 80% to 92% in cases of small perforations including primary procedures.^{7,9–11} In this study, the success rate of the entire group of patients was 88.2%.

Fat material was reported in the literature for post-tympanostomy tube extraction persistent perforations, with 100% success rate,⁶ post traumatic persistent perforations and chronic tubotympanic inactive suppurative otitis media with perforation,⁵ with 91% success rate and for post myringoplasty residual perforation,⁴ with 87.1% success rate. In this study the rate of success for each aetiology group ranged 86.6% to 89%.

Saliba³ recorded 17 dB as a mean improvement of air/bone gap in his study; Liew et al.⁶, recorded improvement in 11 of their 15 patients; Hagemann and Housler⁵, showed improvement in 21 of their 44 patients. Fiorino and Barbieri⁴ recorded a slight non significant improvement in their 31 patients. In this study, the mean improvement in the air/bone gap was 15 dB for the successful cases post operatively.

The failure rate for this study was 8 out of 68 ears (11.75%) with a mean air bone gap of 10 dB and the causes were due to infection, detached fat graft and dehiscence due to undersized grafts. They were reoperated upon after 3 months of complete dryness of the residual perforation by a 2nd trial of fat graft myringoplasty and all healed successfully. Fiorino and Barbieri⁴, attributed the failure causes to: immediate failures due to technical difficulties such as anterior perforations, inadequate graft support, poor vascular supply or infection; and delayed failures due to tympanic membrane atrophy, infections or Eustachian tube dysfunction with the change of tympanic membrane structure. From failure cases (8 ears) we can observe that the failure was mostly in the postoperative precautions of the technique (infection and detachment = 75% of failures). Those causes could be avoided and therefore increase the success rate of the technique if proper and strict postoperative instructions and precautions are followed. On the other hand, the last two failure cases (undersized graft = 25% of failures) can indicate that the fat graft myringoplasty procedure has a minimal technique failure especially if the selection criteria were applied to the patients for this surgery. (Table 3)

Local anaesthesia was used in most of the literature as the procedure is easy, simple, fast and minimally invasive.^{3,4,12} General anaesthesia with laryngeal mask was used in this study for: avoidance of vasovagal responses or patient's discomfort especially in children and unsteady anxious patients. The smooth induction and recovery of general anaesthesia with laryngeal mask prevented Valsalva or pressurization in the early post operative period which may displace the fat graft. General anaesthesia with laryngeal mask has shortened the time consumed for the sedatives and local anaesthetic cream to start its effect. Moreover, the local anaesthetic cream may reach the round window causing vertigo.¹² General anaesthesia gives also better visibility, accessibility to reach technically difficult areas as the anterior margin of the perforation and also allow helping techniques e.g. drilling the anterior meatal wall to visualize the anteriorly located perforations.

In this study, the traumatic, the tubotympanic chronic otitis media, the post tympanostomy tube extraction perforation groups were operated upon after 3 months of dryness and failure of closure, while the post myringoplasty residual perforation cases were operated upon after 6 months of failure of closure.

The advantages of fat graft include: It does not need support from the middle ear side to prevent collapse like underlay grafts especially at the area near the anterior annulus.

Technical operative points during fat grafting (such as graft size in the perforation, degree of lateral bulge of the fat plug and moistening of the lateral side of the graft) are also considered to be important factors of success in the fat grafting procedure.

Fat is also an active material containing angiogenic and survival factors e.g. Monobutylin, prostaglandins, interleukins 1 and 6, cytokines and tumour necrosis factor which, stimulate restoration and repair of the fibrous layer and promote

revascularization which are both essential for survival of the free flap.⁴ Fat graft promotes growth factors including vascular endothelial growth factor, transforming growth factor beta, platelet derived growth factor and fibroblast growth factor which promote the process of the tissue repair.¹³ Fat contains high population of multipotent cells referred as adipose-derived stem cells which are similar in activity to those of the bone marrow derived mesenchymal stem cells in the ability to differentiate into mesenchymal tissues such as endothelial and fibrous types promoting the healing process of the tympanic membrane.¹⁴

5. Conclusion

Fat graft myringoplasty is an easy, simple, fast and minimally invasive procedure for the repair of small tympanic membrane perforations with favourable hearing results. It can be performed under local or general anaesthesia. It can be done for small tympanic membrane perforations due to: trauma, infection, post tympanostomy tube extraction and post myringoplasty persistent residual perforations with good success rate without complication. Increasing the scale and the number of patients for this study would highlight more factors of success and failure for the procedure.

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